

REMARKS

This amendment is responsive to the Office Action of June 16, 2006. Reconsideration and allowance of claims 1-73 are requested.

The Office Action

Claims 1-73 stand rejected under 35 U.S.C. § 102 as being anticipated by Cosman (US 6,405,072).

The Present Application

The present application discloses a surgical system in which the position of a surgical tool is tracked as it performs a medical procedure. For example, the surgical tool could be a medical grinder which grinds out a portion of a patient's bone material to create a recess of predetermined size and shape in order to receive a corresponding implant or insert. As another example, the tool could be a medical drill which is tapping a hole in bone to receive a surgical screw.

An object of interest is defined. The object of interest can be depth and size of the recess that is to be defined in the bone material to receive the insert, a maximum safe drilling distance for the surgical drill, or the like. Soft tissue applications are also contemplated.

During the medical procedure, a scalar distance is determined between the current position of the tool and the object of interest, e.g., the bottom of the recess or bore being defined in the bone by the grinder or drill. The operator is provided with visual, tactile, or audio feedback indicative of the scalar distance. Various visual feedbacks are provided. In one example, the visual feedback is provided on the surgical tool which enables the surgeon to keep his eyes on the surgical site while monitoring the scalar distance. The audio and tactile feedback techniques, being non-visual, permit the surgeon to receive the scalar distance information without removing his eyes from the surgical site.

The Cosman Reference

The **Cosman** reference is directed to an oncology medical device which irradiates a tumor or target 45 with a beam of higher intensity radiation from a

LINAC machine from a plurality of directions. The LINAC machine is built such that as the source of the high energy x-ray beam is rotated, the high intensity x-ray beams from all directions cross a common isocenter point 7.

Cosman is concerned with aligning the tumor or target 45, which is in the interior of the patient and not visible, precisely with the isocenter 7. By way of background, the LINAC machine seeks to deliver a high dose of radiation to the tumor, but a much lower dose to surrounding tissues. If the tumor were irradiated from only a single direction, an entire column of tissue along the trajectory of the beam would be given the high dose of radiation. To avoid this problem, the high intensity beam of radiation is directed through the isocenter from a multiplicity of directions, such that the total cumulative dose of radiation at the isocenter is high; whereas, the total cumulative dose to surrounding tissue is moderate or low.

Because the tumor is internal to the patient, a diagnostic image is generated of the region of the tumor and including external markers such as markers 20, 21, 23, 24. The physical relationship between the markers and the tumor can be determined from the diagnostic image. A camera system C views the markers 20, 21, 23, 24 or different visible markers affixed to the same or a known location relative to the imageable markers. The camera system also monitors the position of markers 40A, 40B, 40C on the gantry of the LINAC machine and markers 30, 31, 32 on the patient couch 11. By the intermediary of the visible markers on the patient and the LINAC system, the relative location of the tumor 45 and the isocenter 7 can be determined.

In preparation for an irradiation treatment, a mechanism 10 is driven either automatically or manually to move the target 45 to the isocenter 7 of the LINAC system. As shown in Figures 9A, 9B, 9C, the deviation between the target and the isocenter is determined and can be displayed on a display unit 39B. After the target has been aligned with the isocenter, the medical treatment is commenced. Optionally, the alignment can be checked by ultrasound or with a radiation detector and lower energy, more diffuse radiation beams from the high energy source. Particularly, high intensity radiation beams are then sent through the isocenter from the various directions, preferably with collimation custom selected for each direction, such that the target located at the isocenter is irradiated from many directions.

Cosman does not disclose or track surgical tools in the sense of a scalpel, biopsy needle, surgical drill or grinder, or the like. The Examiner asserts that Cosman has a visual indicator of the three-dimensional spatial relationship among the patient, a surgical tool, and an imaging device and that the position of the surgical tool of Cosman is continuously tracked during the surgical procedure. It is unclear what the Examiner considers to be a surgical tool. Although Cosman discloses determining the distance between the target 45 and the isocenter 7 (Cosman at col. 7, lines 1-4) and dynamically indicating with a graphic image on a display unit 39 positional relationships among the target 44, the isocenter 7, the patient couch, the LINAC gantry, and the beam B (Cosman at col. 6, lines 39-49; col. 8, lines 31-41), there is no teaching or suggestion in Cosman of providing an indication of a scalar distance between a current position of a surgical tool and an object of interest. The Examiner asserts that Cosman discloses an indication system which includes limitations such as “audio warning or indicator”. The undersigned has conducted a word search for the terms “audio”, and “warning” of the text of the Cosman patent and found no occurrence of either word. A search for the word “indicator” resulted in a reference to indicator or marker 60 in column 9, line 36. However, such indicator is a visual indicator for the cameras and not an indication of distance provided to the user.

The Examiner further asserts that Cosman discloses a haptic shape. By contrast, the undersigned can find no reference to “haptics” in the Cosman patent. The term “haptics”, as defined by the McGraw-Hill Dictionary of Scientific and Technical Terms (2003) means:

haptics [COMPUT SCI] The study of the use of touch in order to produce computer interfaces that will allow users to interact with digital objects by means of force feedback and tactile feedback.
{‘hap-tiks}

The undersigned was unable to find any reference to haptics, haptic feedback, or the science of haptics in Cosman.

The Claims Are Not Anticipated by Cosman

Claim 1 calls for tracking the position of a tool and providing an indication of a scalar distance between the current position of the tool and an object of interest. By contrast, Cosman tracks the distance between a target 45 and an isocenter point 7 and positional relationships among the target 45, the isocenter 7, the patient couch, the LINAC gantry, and the beam B. The isocenter point is a non-physical, conceptual location and is not a tool. Similarly, the LINAC machine is not a surgical tool. Even if one were to consider the LINAC machine to be the tool, then claim 1 is still not met because Cosman does not provide an indication of the scalar distance between the target 45 and the rotating radiation sources or the stationary gantry portion of the LINAC machine. Accordingly, **claim 1 and claims 10-12 and 16-20 dependent therefrom** are not anticipated by Cosman.

Claim 2 calls for tracking the position of a surgical tool that is moved by a surgeon in performing the medical procedure. Cosman discloses no surgical tool which is moved by a surgeon in performing the medical procedure. The rotation, collimator adjustment, and irradiation duration at each of the rotational positions of the high intensity x-ray beam of Cosman are computer-controlled in accordance with a predetermined treatment regimen.

Further, claim 2 calls for determining a scalar distance between the surgical tool and the anatomical target region of the patient and providing a visual indication of such scalar distance. By contrast, the distance between the isocenter and the movable radiation sources of Cosman appears to be a constant and, although Cosman discloses displaying positional relationships among the target 45, the isocenter 7, the couch, the gantry, and the beam, there is no suggestion of displaying a scalar distance between a surgical tool and an anatomical target region. The distance between the target 45 and the isocenter 7 is determined by Cosman, but no display is suggested regarding a scalar distance between the target 45 and the high intensity radiation sources or other movable portions of the LINAC system.

Accordingly, **claim 2 and claims 3-9, 13, and 14 dependent therefrom** are not anticipated by Cosman.

Claim 6 calls for a haptic device. Cosman provides no suggestion of a haptic device.

Claim 7 calls for the scalar distance to be displayed on the surgical tool. Cosman does not suggest placing the display unit **39B** on a surgical tool. Placing the display unit on a surgical tool, such as a surgical drill or grinding tool permits the user to view the determined distance without removing his eyes from the surgical site. This advantage is not achieved in Cosman.

Claim 8 calls for selecting a color for the visual indication based, at least in part, on the scalar distance. Cosman makes no suggestion of color-based visual indications.

Claim 9 calls for selecting the visual indication based at least in part on the scalar distance. Cosman makes no suggestion of selecting a type of visual indication based on distance. Rather, Cosman suggests only a single display format regardless of distance.

Claim 10 calls for the object of interest to include a haptic object. Cosman makes no suggestion of defining a haptic object. Indeed, because there is no hand-used surgical tool in Cosman on which tactile feedback would be advantageous, it is submitted that there is no motivation or apparent reason to add a haptic object to Cosman.

Claims 13 and 14 call for, in addition to displaying the scalar distance, providing a visual indication that the scalar distance is within an acceptable or unacceptable range. No such acceptable/unacceptable range display, in addition to the distance display, is suggested in Cosman.

Accordingly, for the reasons set forth above, it is further submitted that **claims 6-10, 13, and 14** are not anticipated by Cosman.

Claim 15 calls for providing tactile indication of the scalar distance to the user of the surgical tool. By contrast, Cosman discloses no surgical tool or surgical tool portion which is held by a surgeon and through which tactile feedback is provided. Because Cosman provides no tactile feedback and makes no suggestion of providing tactile feedback indicative of distance, it is submitted that claim 15 is not anticipated by Cosman.

Claim 16 calls for providing the indication of scale or distance using vibration. Cosman makes no suggestion of using vibration to indicate distance.

Claim 17 calls for selecting a type of indication of the scalar distance based at least in part on the scalar distance. Cosman provides no suggestion of selecting a type of visual display of distance based on the distance.

Claims 18 and 19 call for supplying an indication of whether the scalar distance is within an acceptable or unacceptable range. Cosman makes no suggestion of providing a display indicative of acceptability/unacceptability of the range of a display distance.

Accordingly, for the reasons set forth above, it is submitted that **claims 16-19** are not anticipated by Cosman.

Claim 21 calls for providing an audio indication of the current scalar distance, i.e., a current scalar distance between a current position of the tool and of the object of interest. Cosman, contrary to the Examiner's assertions, makes no suggestion of audio feedback of any type nor provides any motivation to provide audio feedback of any type, much less an audio signal which is indicative of current scalar distance. Using an audio signal to indicate scalar distance to a surgeon performing a manually controlled surgical operation is advantageous in that the surgeon can keep his eyes on the surgical site and still be informed of the current scalar distance. Cosman neither discloses these claimed concepts nor the advantages thereof.

Accordingly, it is submitted that **claim 21 and claims 22-31** are not anticipated by Cosman.

Claim 22 further calls for selecting a type of audio indication. Cosman makes no suggestion of providing an audio indication, much less selecting among types of audio indications.

Claim 23 calls for providing the audio indication via an audio device. Cosman neither discloses an audio device nor an audio indication.

Claim 24 calls for an audio device disposed on a haptic device. Cosman discloses no haptic device and no audio device.

Claim 25 calls for the audio signal to change proportionately to changes in the current scalar distance. Cosman provides no suggestion of an audio signal, much less an audio signal which changes with distance.

Claim 26 calls for selecting an audio indication based at least in part on scalar distance. Cosman makes no suggestion of providing an audio indication, much less selecting among potential audio or other indications based on distance.

Claim 27 calls for the object of interest to include a haptic object. Cosman makes no suggestion of or reference to a haptic object. There is no motivation to provide a haptic object in the radiation treatment system of Cosman nor does Cosman suggest any advantage which a haptic object would provide in the Cosman radiation treatment system.

Claims 30 and 31 call for further providing audio indications indicating acceptable or unacceptable ranges. Cosman, again, provides no audio indication.

Accordingly, it is further submitted that **claims 22-31** are not anticipated by Cosman.

Claim 32 calls for a surgical tool at least a part of which moves through the internal anatomy of a patient to perform the medical procedure. In Cosman, only a beam of radiation passes through the patient during the irradiation procedure.

Claim 32 further calls for providing an indication of a current scalar distance between the surgical tool and the object of interest. Cosman provides no indication of a current scalar distance between the rotatable radiation beam source or other portions of the LINAC system during the medical procedure.

Accordingly, it is submitted that **claim 32 and claims 33-37, 39-51, 64, and 65 dependent therefrom** are not anticipated by Cosman.

Claim 39 calls for selecting a color for a visual indication based on scalar distance. Cosman makes no suggestion of selecting color of a visual display based on distance.

Claim 40 calls for selecting among a plurality of visual indications based on distance. Cosman, by distinction, shows only a single distance display and makes no suggestion of selecting among a plural of potential indications.

Claim 41 calls for a haptic object. Cosman makes no suggestion of a haptic object and provides no motivation which would lead one to add a haptic object to the Cosman irradiation system.

Claim 42 calls for the object of interest to define a portion of the anatomy which is removed by the surgical tool. Cosman removes no portion of the anatomy. Rather, Cosman irradiates a target region **45** of the anatomy.

Claims 44 and 45 call for the providing a visual indication of whether the scalar distance is within an acceptable or unacceptable range. Cosman, by distinction, provides no indication of acceptable or unacceptable distance ranges.

Claim 46 calls for the indication of scalar distance to be tactile. Cosman makes no suggestion of tactile feedback.

Claim 47 calls for vibration of a device in contact with the user. Cosman makes no suggestion of a vibration device.

Claim 48 calls for selection of a type of indication based, at least in part, on scalar distance. Cosman makes no suggestion of selecting among types of indications based on distance indications.

Claims 49 and 50 call for an indication indicating distance within an acceptable or unacceptable range. Cosman provides no indication whether any determined distance is within an acceptable or unacceptable range.

Accordingly, for the above reasons, it is further submitted that **claims 39-51** are not anticipated by Cosman.

Claim 52 calls for tracking position changes of a movable medical tool and determining a current scalar distance between a current position of the tool and an object of interest as the tool moves relative to the object of interest during a medical procedure. Cosman does not track the position of a movable medical tool nor determine a current scalar distance between a current position of the tool and the object of interest. Further, claim 52 calls for an audio indication of the current scalar distance. Cosman suggests no such audio indication.

Accordingly, it is submitted that **claim 52 and claims 53-63 dependent therefrom** are not anticipated by Cosman.

Claim 53 calls for selecting a type of audio indication. Cosman makes no suggestion of selecting a type of audio indication.

Claim 54 calls for an audio device associated with a computer-assisted surgery system. Cosman discloses no computer-assisted surgery system or audio device associated therewith.

Claim 55 calls for a haptic device. Cosman makes no suggestion of a haptic device.

Claim 56 calls for an audio device disposed on a surgical tool in proximity to the anatomy of a patient. Cosman discloses no audio device disclosed on a surgical tool in proximity to the anatomy of a patient.

Claim 57 calls for selecting an audio indication based, at least in part, on scalar distance. Cosman makes no suggestion of selecting an audio indication.

Claim 58 calls for a haptic object. Cosman does not disclose a haptic object.

Claims 61 and 62 call for providing an audio indication indicating whether the scalar distance is within an acceptable or unacceptable range. Cosman does not disclose an audio acceptable or unacceptable range signal.

Claim 64 calls for the surgical tool to remove bone material. Cosman makes no suggestion of a surgical tool which removes bone or other anatomical material.

Claim 65 calls for a haptic device. Cosman discloses no haptic device.

Accordingly, for the above reasons, it is further submitted that **claims 53-65** are not anticipated by Cosman.

Claim 66 calls for a changing indication of scalar distance as the tool moves during the medical procedure. By contrast, the distance between the target 45 and the isocenter 7 is changed during setup for the medical procedure, but the two remain fixed in alignment during the irradiation procedure.

Accordingly, **claim 66 and claims 67-73 dependent therefrom** are not anticipated by Cosman.

Claim 68 calls for the distance indication to be an audio indication. Cosman does not disclose an audio distance indication of scalar distance.

Claim 69 calls for a tactile distance indication. Cosman does not disclose a tactile distance indication.

Claim 70 calls for selecting a type of indication based on distance. Cosman makes no suggestion of selecting a type of indication based on distance.

Claims 71 and 72 call for indicating whether the scale or distance is within an acceptable or unacceptable range. Cosman makes no suggestion of an acceptable or unacceptable distance range signal.

Accordingly, it is submitted that **claims 67-72** are not anticipated by Cosman.

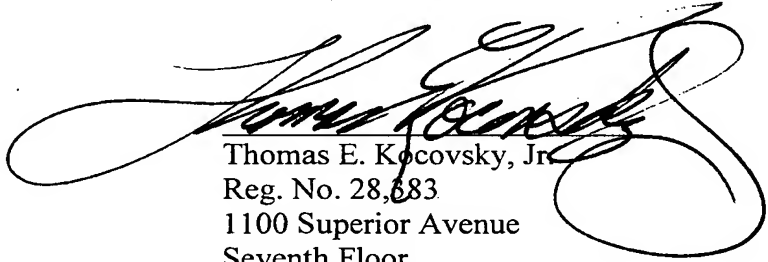
CONCLUSION

For the reasons set forth above, it is submitted that claims 1-73 (all claims) are not anticipated by Cosman. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, he is requested to telephone Thomas Kocovsky at (216) 861-5582.

Respectfully submitted,

FAY, SHARPE, FAGAN,
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A large, stylized handwritten signature in black ink, likely belonging to Thomas E. Kocovsky, Jr., is written over the printed name and address.

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